UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



MEMORANDUM

4/2/2020

SUBJECT: Product Chemistry Review for SiS 200D RTU, EPA Reg. No.: 75174-RN

FROM: Narayanan Parthasarathy

Chemistry and Toxicology Team

Product Science Branch

Antimicrobials Division (7510P)

THRU: Karen P. Hicks, Team Leader

Chemistry and Toxicology Team

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Antimicrobials Division (7510P)

TO: Kathryn Montague, PM Team 31 / Karen Leavy

Regulatory Management Branch I Antimicrobials Division (7510P) Registrant: **SiShield Technologies Inc.** Action code: A540

Agency Due Date: 5/11/2020

DP No.: 455400

Submission No.: 1043182

E-Sub No.:

Classification: EP

Process: Nonintegrated system

Pesticide type: Disinfectant

MRID(s):51009501-51009504 & 50285404

	•	Formulation from label	
PC code(s)	CAS No.	Active Ingredient(s)	% weight
069105	68424-85-1	Alkyl dimethyl benzyl ammonium chloride (50%C ₁₄ , 40%C ₁₂ , 10% C ₁₆)	
069166	5538-94-3	Dioctyl dimethyl ammonium chloride	0.0150%
069165	32426-11-2	Octyl Decyl dimethyl ammonium chloride	0.0375%
069149	7173-51-5	Didecyl dimethyl ammonium chloride	0.0225%
107401	27668-52-6	3-(trimethoxysilyl)propyldimethyloctadecyl ammonium chloride**	0.3280%
		Other Ingredients	99.5470%
		Total	100.0000%
107403	19911-50-7	3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride** **(Produced by hydrolysis)	0.2990%

Comments/Molecular Structure

3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride**

↓ Hydrolysis

3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride + Methanol

I. BACKGROUND

On behalf of the Registrant, SiShield Technologies Inc., KRK CONSULTIG LLC has submitted an application for pesticide registration for their product: SiS 200D RTU, EPA Reg. No. 75174-RN.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-27 – Formulator's Exemption Statement	⊠	
EPA FORM 8570-35 – Data Matrix (12/26/2019)	×	
Cover letter (11/15/2019)	×	
Transmittal document	X	
Proposed CSF BASIC, (1/3/2020)	\boxtimes	
Proposed label, (1/3/2020)	X	
Certification for Pilot Fragrance Notification Program		
REFERENCED: CSF	I	
Comments:		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated			\boxtimes		\boxtimes
Integrated					
Active Ingre	edients(s)		Nominal	Upper limit	Lower limit
Alkyl dimethyl benzyl ammonium	chloride (50%C	_{14,} 40%C _{12,} 10%	0.0500%	0.0550%	0.04500%
C ₁₆)				
Dioctyl dimethyl am	monium chlorid	e	0.0150%	0.01650%	0.01350%
Octyl Decyl dimethyl a	ımmonium chloi	ride	0.0375%	0.04125%	0.03375%
Didecyl dimethyl ammonium chloride			0.0225%	0.02475%	0.02025%
3-(trimethoxysilyl) propyldimethyloctadecyl ammonium			0.328%	0.359%	0.291%
chlor	ide				
↓Hydro	olysis				
3-(trihydroxysilyl) propyldimethyloctadecyl ammonium chloride		0.2990%	0.3260%	0.2680%	
			1		1

	YES	NO	N/A
1. The certified limits of all ingredients are within 40 CFR			
standard certified limits.			
2. Wider certified limits were requested, and rationale was			\boxtimes
accepted.			
3. The nominal concentration(s) of the active ingredient is in			
agreement with the label.			
4. The chemical IDs and analytical information for density, pH,			
and flammability are consistent with Series 830 Group B data.			
5. All inert ingredients are approved for non-food use pesticide			
formulations.			
6. The impurities present >0.1% are identified.			
7. Impurities of toxicological significance have an upper certified			
limit.			

b. Product Label:

	Yes	NO	N/A
The formula contains one of the following:			
1. 10% or more of petroleum distillate			
2. 1.0% or more of methyl alcohol			
3. Sodium nitrite at any level			
4. A toxic list 1 inert at any level			
5. Arsenic in any form			
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote			\boxtimes
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label			\boxtimes
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.			
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.			

IV. Additional Findings

- Basic CSF (1/3/2020) is acceptable. The registrant had provided data to support Product Chemistry data requirements, Group A & B 830 guidelines for end-use, non-integrated, non-food use disinfectant, Sis 200D RTU, EPARN 75174-RN.
- 2. Storage Stability (830.6317 guideline) and Corrosion Characteristics (830.6320 guideline): Test substance was stored in a glass container at 54 ± 2°C for a total of 14 days (Please refer to MRID 51009504, dated May 10, 2019). Total Quaternary Ammonia (%) was determined in duplicates at Day 0 and Day 14. However, EPA Application from 8570-1 dated 11/15/2019 indicates that type of container (package) is plastic which is same in the proposed label. Therefore, Storage Stability and Corrosion Characteristics studies conducted using glass container is not compatible with plastic container. Therefore, the registrant had not met with data requirements for Storage Stability and Corrosion Characteristics.

V. Conclusion

Basic CSF (1/3/2020) is acceptable. The registrant had provided data to support Product Chemistry data requirements, Group A & B 830 guidelines for end-use, non-integrated, non-food use disinfectant, Sis 200D RTU, EPARN 75174-RN, except for Storage Stability (830.6317 guideline) and Corrosion Characteristics (830.6320 guideline) which must be submitted upon completion.

VI. Table A: Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	51063901
830.1600	Description of materials	Acceptable	51063901 &CSF
830.1620	Description of production process	Not applicable, non-integrated	N/A
830.1650	Description of formulation process	Acceptable	51063901
830.1670	Discussion of formation of impurities	Acceptable	51063901
830.1700	Preliminary analysis	Not applicable, non-integrated	N/A
830.1750	Certified limits	Acceptable	51063901 & CSF
830.1800	Enforcement analytical method	Acceptable	51063901
830.1900	Submittal of samples	Available upon request	51063901

VII. Table B: Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment	Status	MRID
830.6302	Color	Not required for end use product	Not applicable	N/A
830.6303	Physical state	liquid	Acceptable	51063902 & Self certification EPA form 8570-36
830.6304	Odor	Not required for end use product	Not applicable	N/A
830.6313	Stability to normal & elevated temperatures, metals & metal ions	The product is not TGAI	Not applicable	N/A
830.6314	Oxidation/Reduction	Mild reaction with reducing agent	Acceptable	51063902 & Self certification EPA form 8570-36
830.6315	Flammability	The product is 99.9625% water	Not applicable	51063902 & Self certification EPA form 8570-36
830.6316	Explodability	The product is 99.9625% water	Not applicable	51063902 & Self certification EPA form 8570-36
830.6317	Storage stability	Accelerated Storage Stability at $54 \pm 2^{\circ}$ C for 14 days was conducted.	Not acceptable	51009504
830.6319	Miscibility	Product will be diluted with water only	Not applicable	51009502 & Self certification EPA form 8570-36
830.6320	Corrosion characteristics	Corrosion Characteristics were examined after storage at 54 ± 20C for 14 days	Not acceptable	51009504
830.6321	Dielectric breakdown voltage	Product not used near electrical equipment	Not applicable	51063902 & Self certification EPA form 8570-36
830.7000	pH	5.0 – 6.0	Acceptable	51063902 & Self certification EPA form 8570-36
830.7050	UV/Visible absorption	Not required for MUP or EP	Not applicable	N/A
830.7100	Viscosity	0.89 cps spindle #1@ 25°C	Acceptable	51063902 & Self certification EPA form 8570-36
830.7200	Melting point	Not required for MUP or EP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP or EP	Not applicable	N/A
830.7300	Density/relative	0.993g/ml	Acceptable	51063902 & Self certification EPA form 8570-36
830.7370	Dissociation constants in water	Not required for MUP or EP	Not applicable	N/A
830.7520	Particle size	Not required for MUP or EP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP or EP	Not applicable	N/A

830.7840/ 7860	Water solubility	Not required for MUP or EP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP or EP	Not applicable	N/A

CONFIDENTIAL APPENDIX

75174-RN
DP# 455400
SiShield Technologies Inc
Sis 200D RTU

NOTE TO PM

MRIDs 510639021 & 51063902 are paper submissions and will be loaded into DOCUMENTUM

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